

REMARKS

Claims 1-21 are currently pending in the application; claims 1 and 13 are independent claims.

The Examiner has rejected claims 1-5 and 9-15 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,755,715 to Stern et al., (hereinafter "Stern") in view of U.S. Patent No. 5,405,337 to Maynard (hereinafter "Maynard") and in further view of U.S. Patent No. 6,334,093 More (hereinafter "More"). Applicant respectfully submits the rejection is overcome in light of the following remarks.

The teachings of Stern, Maynard and More, taken alone or in any combination, fail to teach or suggest the invention defined by the instant claims.

Claim 1 is directed to a method for measuring temperature at a site within a patient during a medical procedure. The method comprises, *inter alia*, providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor, determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system, and providing a temperature measurement signal to the position sensor. By means of the foregoing steps, the claimed invention is capable of facilitating a physician to control the temperature of the ablated tissue and at the mean time pinpoint the location of the tissue to be ablated. Independent claim 13 also recites the above features.

Stern teaches an apparatus for ablating heart tissue using energy emitted from an energy source. Stern does not in any way teach or suggest a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor. Specifically,

Stern is directed to the method and apparatus of processing temperature related data to control the tissue ablation.

The Examiner alleges that Stern teaches a position sensor and the step of placing the position sensor at a site of interest, citing Col. 1, Lines 48-67 and Col. 2 Lines 1-49 of the Stern disclosure (see, Item 3, Lines 5-9 of the Action). However, after thoroughly reviewing Stern, Applicant respectfully submits that neither the cited part of Stern nor any other part of Stern teach a position sensor or the step of providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor. Applicant assumes that the Examiner has interpreted the temperature sensor (30) carried by the distal tip (16) of the catheter (14) as a disclosure of the position sensor, in which case Applicant respectfully submits that the temperature sensor in the form of a bead thermistor is by no means a position sensor as defined by the present application.

Confusingly, the Examiner further acknowledges that Stern does not specifically disclose the use of a position sensor (see, Page 3, Lines 5-6 of the Action). Applicant agrees with the Examiner in this regard. Applicant further respectfully submits that, in any event, Stern fails to disclose a position sensor and the concomitant steps in connection with the position sensor, as recited by claims 1 and 13.

However, the Examiner further alleges that Stern discloses thermal mapping and techniques which indicate position of the medical device (see, Item 3, Lines 9-10 and Page 3, Lines 4-5 of the Action) and Maynard teaches positional sensors and sensors for measuring environmental parameters (see, Page 3, Lines 7-9 of the Action). Based on the above allegation, the Examiner has combined the teachings from Stern and Maynard to reject the pending claims

of the present application. Applicant respectfully disagrees with the Examiner's above rationale in this regard.

In the first instance, the general description of thermal mapping in Stern does not disclose the determination of the location of the medical device. Stern teaches a memory element for storing a temperature versus time curve for heating tissues. The temperature curve includes a first region of temperature values over time that are below tissue ablating temperatures to allow thermal mapping and the temperature set curve coordinates thermal mapping with tissue ablation (see, Col. 2, Lines 24-30). Stern further describes how the parameter T_{SET} is used to define a complex curve to accommodate thermal mapping before thermal ablation, including using T_{SET} in different value ranges for thermal mapping (see, Col. 9, Line 63 to Col. 10, Line 12). Thus, it is the Applicant's understanding that the thermal mapping is a data processing procedure or a form of data presentation based on different values of a thermal parameter. If the Examiner insists that the thermal mapping in Stern indicates the determination of the position of the medical device, Applicant respectfully requests the Examiner to point out where Stern specifically offers such disclosure.

In addition, turning to Maynard, it discloses a shape memory alloy (SMA) actuator film used to control the steering of a tube-shaped medical device, such as a catheter. The Examiner has relied on the disclosure at Col. 8, Lines 3-25 of Maynard for the alleged teaching of a position sensor, and the steps of determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system and providing a temperature measurement signal to the position sensor. Applicant respectfully disagrees.

Maynard generally describes, at Col. 8, Lines 3-25, that position sensors and sensors for measuring environmental parameters can be integrated with other components in a flexible sheet to provide a compact electrical device. However, such general description does not disclose the step of determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system. Although the Examiner contends that Maynard teaches the application of a magnetic field, Maynard does not teach that the magnetic field is in conjunction with the position sensor to determine the position and/or orientation coordinates of the position sensor. Maynard only generally discloses sensors which may be integrated in the flexible sheet for measuring magnetic fields.

Furthermore, the Maynard device is applied to control the steering of the tube of the catheter, and accordingly, the device is arranged at the stem of the catheter to control the movement of the tip of the catheter. Thus, Maynard does not teach providing a temperature measurement signal to the position sensor, because the temperature at Maynard's position sensor is not directly related to the temperature at the tip of the catheter for ablating tissue. In other words, a physician will not rely on the temperature measurement at the control device for steering the catheter to determine how the temperature at the tip of the catheter should be changed for ablating tissue.

In addition, as discussed above, the thermal mapping disclosed by Stern fails to identify any connection to the determination of the position and/or orientation coordinates of the position sensor, which the Examiner relied on to combine Stern and Maynard. Thus, Applicant respectfully submits that such combination is not proper.

More is directed to a method of measuring temperature differences on the order of micro-degrees centigrade, by utilizing predictable behavior in the relative time drift of thermal

offset curves. More does not remedy the underlying deficiencies of Stern and Maynard relative to independent claims 1 and 13.

Therefore, the hypothetical combination of Stern, Maynard and More, taken alone or in any combination, fail to teach or suggest the combination of features recited by claims 1 and 13, from which all the other claims depend. Accordingly, the rejection of claims 1-5 and 9-15 under 35 U.S.C. § 103(a) based on the combination of Stern, Maynard and More is overcome, and withdrawal thereof is respectfully requested.

The Examiner has further rejected claims 6-8 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Maynard, More and U.S. Patent No. 5, 833,608 to Acker (hereinafter "Acker"). Applicant respectfully traverses the rejection.

Claim 1, from which claims 6-8 depend, is discussed above. Stern, Maynard and More are discussed above relative to claim 1.

Acker is relied on to allegedly teach the additional limitations recited by claims 6-8, such as AC magnetic field and temperature measurement signal. However, Acker does not remedy the underlying deficiencies of Stern, Maynard and More. Thus, the hypothetical combination of Stern, Maynard, More and Acker, taken alone or in any combination, fails to teach or suggest the combination of features recited by claim 1. Accordingly, the rejection of claims 6-8 under 35 U.S.C. § 103(a) based on the combination of Stern, Maynard, More and Acker is overcome, and withdrawal thereof is respectfully requested.

The Examiner has rejected claims 16-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Maynard, More and U.S. Patent No. 5, 638,418 to Douglas et al., (hereinafter "Douglas"). Applicant respectfully traverses the rejection.

Claim 13, from which claims 16-21 depend, is discussed above. Stern, Maynard and More are discussed above relative to claim 13.

Douglas is relied on to allegedly teach the additional limitations recited by claims 16-21, such as applying a resistance drift factor to the resistance value. However, Douglas does not remedy the underlying deficiencies of Stern, Maynard and More. Thus, the hypothetical combination of Stern, Maynard, More and Douglas, taken alone or in any combination, fails to teach or suggest the combination of features recited by claim 13. Accordingly, the rejection of claims 16-21 under 35 U.S.C. § 103(a) based on the combination of Stern, Maynard, More and Douglas is overcome, and withdrawal thereof is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Paul J. Esatto, Jr.
Registration No. 30,749

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza - Suite 300
Garden City, New York 11530
(516) 742-4343
PJE/DJD/HC/ech